UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,730	10/19/2001	Paul Arthur Mason	10071-018-999	9664

20583 7590 09/26/2003

PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER
GHALI, ISIS A D

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,730	MASON, PAUL ARTHUR	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *7-11,17-21 and 28-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,12,17 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4-8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants' IDS, filed 06/02/2003; and response, filed 07/18/2003.

Election/Restrictions

1. Applicant's election with traverse of Group I, species (a) for the method, and species (a) for the local anesthetic, in Paper No. 7 is acknowledged. The traversal is on the ground(s) that Groups I and II have the same subject matter and it is not serious burden on the examiner to search both groups. The method of inducing local anesthesia as recited in claims 22-32 are not mutually exclusive with the method of treating pain associated with a non-intact skin as recited in claims 33-43. Applicant argues that a patch and package or method of use that comprises one of the local anesthetic are not mutually exclusive with those comprises another of the local anesthetics.

This is not found persuasive because inventions II and I are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as hydrogel per se or as a base for any topical formulation, such as ointment, and the inventions are deemed patentably distinct since there is nothing on this record

to show them to be obvious variants. The species of the method are mutually exclusive species because treating pain and induction of anesthesia are two different methods of use since the induction of anesthesia can be carried out onto healthy intact skin to perform surgical procedure, while treating pain associated with non-intact skin requires the presence of cut, wound, or ulcer, etc. The dose of the anesthetic that could be effective to carry out one method would not be the same for the other. When the drug is applied to non-intact skin, it is more liable to reach the systemic circulation and provide some systemic actions, and in such case pain relief would not be caused only by the anesthetizing the nerve endings, but also caused by the systemic analgesic effects of the drugs. Regarding the species of the local anesthetics, they are mutually exclusive species since they are different group of drugs, having different structures and different mechanisms of action. Local anesthetics cause slow propagation of nerve impulses by reducing the rate of rise of action potential and the rate of repolarization. Local anesthetics block nerve conduction by interfering with the permeability of the cell membrane in response to partial depolarization and thus stabilize the membrane at the resting potential. Local anesthetics displace calcium from a site near the sodium channel and then block the adjacent sodium channel. Because of the lipophilicity of the local anesthetics, they incorporate into the cell membrane, preventing the opening of the pores and thus interfering with the passage of the electrolytes. The mechanism of action of antidepressants is totally different from local anesthetics since the antidepressants are histamine receptor blocking agents and have alpha-adrenergic properties and blocks the re-uptake of serotonin. NMAD receptor antagonists are

dissociative analgesics that produce stage similar to neuroleptic analgesia. Regarding opioids, they alter the level of neurotransmitters at the presynaptic neurons.

The search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner. While searches may seem to be overlapping, nevertheless, they are extensive because the patent examiner searches the databases mostly literally. Rarely do applicants present claims to an inventions where the distinctness of the invention are readily clear such as a chemical compound and a gene sequence. It is the responsibility of the examiner to enforce 35 USC 101, which allows the applicant to obtain a patent for a single invention. In the opinion of the examiner the applicants present two distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 7-11, 17-21, 28-53 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claims 1-6, 12-16, 22-27 are included in the prosecution.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 3-6, 22, 24-27 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,455,066 ('066).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US '066 disclosed patch comprising permeable backing (breathable), and a carrier formulated with at least one local anesthetic (col.8, lines 4-6; col.9, lines 11, 18, 64-65). The carrier comprises polyvinyl pyrrolidone hydrogel (col.8, lines 27-28; 67). The preferred local anesthetic is lidocaine (col.5, lines 30-39). The formulation comprises preservatives (col.6, line 57). The backing is derived from polyester (col.9,

lines 12-13). The patch is used for local anesthetization of skin prior to minor surgical procedures (col.11, lines 28-29).

5. Claims 1, 3-6, 12-16 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,469,227 (227).

US '227 disclosed a non-occlusive adhesive skin patch used to relieve topical discomfort (abstract; col.2, lines 5-8). The patch comprises a breathable backing of polyester coated with a therapeutic formulation (col.3, lines 7-16, 35-36, 42, 50-56). The patch is packaged (col.4, line 1; col.18, lines 45-47). The therapeutic formulation is hydrogel that comprises local anesthetic such as lidocaine, and polymer such as polyvinyl pyrrolidone (col.4, lines 13-15, 28, 45; col.7, lines 1-2; col.11, lines 43-45). The patch further comprises alcohol, which reads on the preservative (col.6, line 6).

6. Claims 1, 3-6, 22, 24-27 are rejected under 35 U.S.C. 102(e) as being anticipated by PGBP 2003/0027833 ('833).

PGPB '833 disclosed a method and a delivery system for administration of at least one local anesthetics agent to a patient by applying the delivery system to the skin (abstract; page 2, 0017, 0019). The drug delivery device comprises a backing layer laminated to a drug reservoir (page 2, 0023; page 8, 0088). The reservoir comprises a hydrogel comprising hydrophilic polymers comprising polyvinyl pyrrolidone (page 6, 0070, 0071; page 8, 0086; page 9, 0091). The reservoir comprises the local anesthetic and a preservative (page 8, 0083). The backing layer is preferably breathable and made

of polyester or polyether (page 9, 0092). The preferred local anesthetic is lidocaine (page 4, 0048).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 2, 12-16, and 23 are rejected under 35 U.S.C. 103(a) as being obvious over US' 066 in view of US 5,405,366 ('366).

The applied reference US '066 has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29,

1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The teachings of US '066 are discussed under 102 rejections above.

However, US '066 does not teach the patch is sterile, as claimed in claims 2 and 23, or packaged, as claimed in claims 12-16.

US '366 teaches a non-stingy adhesive hydrogel that can be formed into patches for long term application of a pharmaceutically active agents to a patient and having both adhesive and cohesive properties (abstract; col.4, lines 30-31). The patches delivered by the hydrogel are sterile and their packaging should be adaptable to ensure sterility (col.5, lines 36-55). The patch must be sterile and the patch and the associated structural and packaging material are sterilized (col.5, lines 35-55). The hydrogel comprises polyvinyl pyrrolidone (col.6, lines 35-37, 47-49). The hydrogel further comprises preservative and anesthetics (col.8, lines 5, 10). The hydrogel is coated on a backing of polyester (col.9, lines 1-13).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver the patch comprising polyvinyl pyrrolidone hydrogel and local anesthetic as disclosed by US '066 and package the patch and sterilize it as disclosed by US '366, motivated by the teaching of US '366 that the patch must be sterile and the packaging ensures sterility, and also that the patch and the associated structural and packaging material all can be sterilized, with reasonable expectation of

having a sterile patch that deliver local anesthetic to the skin of the patient in need with success.

9. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '227 in view of US '366.

The teachings of US '227 and US '366 are discussed above.

However, US '227 does not teach that the patch is sterile.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver the patch comprising polyvinyl pyrrolidone hydrogel and local anesthetic as disclosed by US '227 and sterilize the patch as disclosed by US '366, motivated by the teaching of US '366 that the patch must be sterile and that the patch and the associated structural and packaging material all can be sterilized, with reasonable expectation of having a sterile patch that deliver local anesthetic to the skin of the patient in need with success.

10. Claims 2, 12-16, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over PGPB '833 in view of US '366.

The teachings of PGPB '833 and US '366 are discussed above.

However, PGPB '833 does not teach the patch is sterile, as claimed in claims 2 and 23, or packaged as claimed in claims 12-16.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver the patch comprising polyvinyl pyrrolidone hydrogel and

local anesthetic as disclosed by PGPB '833 and package the patch and sterilize it as disclosed by US '366, motivated by the teaching of US '366 that the patch must be sterile and that the packaging ensures sterility, and also that the patch and the associated structural and packaging material all can be sterilized, with reasonable expectation of having a sterile patch that deliver local anesthetic to the skin of the patient in need with success.

11. Claims 22, 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '227.

The teachings of the reference are discussed above, however, the reference does not explicitly teach the method for inducing local anesthesia in a mammal, but implicitly teaches the method of anesthetizing the skin by teaching the administration of local anesthetic to the skin in order to relieve local discomfort.

Thus, it would have been obvious to one having ordinary skill in the art at he time of the invention to use the device and the method disclosed by US '227 to induce local anesthesia motivated by the teaching of US '227 that the patch is safe, effective and convenient as well as it can protect the skin inflicted with topical disorder and facilitate the healing of the disorder by diminishing the contact with the contaminant from the environment, with reasonable expectation of the delivered patch to induce local anesthesia to patient in need of such a relief.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Isis Ghali
Examiner
Art Unit 1615

Isis Ghali